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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN LINK, CLAUDIA A. ROBBINS, BARRY E. BOYES, and RHONDA TAYLOR

Appeal 2010-000825
Application 10/804,938
Technology Center 1600

Decided: May 27, 2010

Before ERIC GRIMES, DONALD E. ADAMS, and STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a method of preparing cRNA substantially free of contaminants. The Patent Examiner rejected the claims on the ground of obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 1, 3-15, 20 and 21, which are all the pending claims, are on appeal. Claim 1 is representative and reads as follows:

1. A method of preparing a cRNA sample substantially free of contaminants, comprising the following steps:

(a) preparing a cRNA sample;

(b) adding an organic solvent to said preparation of (a);

(c) contacting a cRNA isolation column with the organic preparation of step (b), wherein said cRNA isolation column comprises a membrane selected from the group consisting of polysulfone treated with hydroxypropylcellulose, PVDF (polyvinylidene fluoride), nylon, nitrocellulose, polysulfone, polysulfone and polyvinylpyrrolidone, PVP (polyvinylpyrrolidone), and composites thereof;

(d) adding to a preparation of step (c) one or more DNase enzymes;

(e) adding to a preparation of step (d) a wash buffer comprising a chaotropic salt; and

(f) eluting said cRNA in a purified form from said column of step (c).

The Examiner rejected the claims as follows:

- claims 1, 3-6, 10-15, 20 and 21 under 35 U.S.C. § 103(a) over Sambrook,[1] Wang '727,[2] Wang '742[3] and Pall Life Sciences[4]; and
- claims 7-9 under 35 U.S.C. § 103(a) over Sambrook, Wang '727, Wang '742, Pall Life Sciences and Waggoner[5].

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[1] Joseph Sambrook et al., *Molecular Cloning A Laboratory Manual*, 2nd ed., pp. 7.12-15, 7.23-29 (Cold Spring Laboratory Press 1989).
[2] Alice N. Wang et al., U.S. Patent No. 5,219,727, issued Jun. 15, 1993.
[3] I-Fan Wang et al., U.S. Patent No. 5,906,742, issued May 25, 1999.
[4] Pall Life Sciences Bulletin #FAM-1050-C, *MMM Asymmetric Super-Micron Membranes*, Pall Corp., Filterite Advanced Materials Div. (San Diego 2002).

OBVIOUSNESS

The Issue

The Examiner's position is that Sambrook taught a method of preparing RNA substantially free of contaminants. (Ans. 5.) The Examiner found that Sambrook's method used DNAse I and a chaotropic agent, and contacted an RNA isolation "membrane" column with an RNA containing precipitate, and performed chromatography to obtain the RNA. (*Id.* at 6.) The Examiner found that Sambrook's chromatography was "performed in a column comprising a membrane; namely a Pasteur pipette comprising an oligo(dT) cellulose and a glass wool plug." (*Id.*) The Examiner interpreted "membrane" to include a glass wool plug "because a 'wool' comprises a multi-fiber interwoven structure (i.e., a membrane) having spaces between individual fibers (i.e., pores)." (*Id.*) The Examiner found that Wang '742 taught asymmetric microfiltration membrane materials for filtering biological samples (*id.* at 8), and concluded it would have been obvious to replace Sambrook's glass wool plug with the membrane taught by Wang '742 (*id.*).

Appellants "disagree with the Examiner's conclusion that [Sambrook's] glass wool plug constitutes a membrane as that term is used in the context of the instant claims." (App. Br. 11.) Further, according to the App. Br., "Appellants have not found, and the Examiner has failed to identify, any teaching or suggestion in Wang et al. '742 of a cRNA purification method." (*Id.* at 13.)

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[5] Alan S. Waggoner, U.S. Patent No. 5,627,027, issued May 6, 1997.

The issues with respect to this rejection are:

whether the claim term "membrane" is reasonably interpreted to include Sambrook's glass wool plug, in light of the Specification or other evidence; and

whether the evidence supports the finding that Wang '742 disclosed or suggested using a membrane as an RNA isolation column.

Findings of Fact

1. Sambrook described an RNA purification method using oligo(dT)-cellulose in a pasture pipette plugged with sterile glass wool. (Sambrook, 7.26.)
2. The Examiner interpreted "membrane" to include a glass wool plug "because a 'wool' comprises a multi-fiber interwoven structure (i.e., a membrane) having spaces between individual fibers (i.e., pores)." (Ans. 6.)
3. The Examiner relied on the following definition of "membrane":

   > a microporous structure that acts as a highly efficient filter that allows passage of water, but rejects suspended solids and colloidals; depending on membrane type, ions and small molecules might or might not be rejected.

   (Ans. 4, citing p2pays.org.)
4. The Examiner relied on the Abstract of Wang '742's disclosure of membranes used to filter biological samples to support the obviousness rejection. (Ans. 8.)
5. Wang '742 disclosed "a sulfone polymer membrane . . . that can separate solids (i.e., blood cells) from a liquid (i.e., plasma) without the need for centrifugation." (Wang '742, Abstract.)

Principles of Law

> [T]he PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification.

In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

> Absent an express definition in their specification, the fact that appellants can point to definitions or usages that conform to their interpretation does not make the PTO's definition unreasonable when the PTO can point to other sources that support its interpretation.

Id. at 1056.

"Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), cited with approval in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417-18 (2007).

Analysis

We find no express definition of "membrane" in the Specification. However, we agree with Appellants that the claim term "membrane," viewed in light of the Specification, does not include a plug of glass wool.

Further, the definition from p2pays.org, which the Examiner relied on, does not support the Examiner's interpretation as required by *Morris*. *See* 127 F.3d at 1056. p2pays.org defined a membrane as a "microporous

structure." (FF 3.) The Examiner described wool as a "multi-fiber interwoven structure" having "pores." (FF 2.)

The ordinary meaning of pore[6] is an opening or aperture. *E.g.*:

The American Heritage® Dictionary of the English Language, Fourth Edition, Houghton Mifflin Company (2000).

> 1. A minute opening in tissue, as in the skin of an animal, serving as an outlet for perspiration, or in a plant leaf or stem, serving as a means of absorption and transpiration.
> 2. A space in rock, soil, or unconsolidated sediment that is not occupied by mineral matter and that allows the passage or absorption of fluids: Water seeped into the pores of the rock.

Collins English Dictionary – Complete and Unabridged HarperCollins Publishers (2003).

> 1. (Life Sciences & Allied Applications / Anatomy) Anatomy Zoology: any small opening in the skin or outer surface of an animal
> 2. (Life Sciences & Allied Applications / Botany) Botany: any small aperture, esp. that of a stoma through which water vapour and gases pass
> 3. (Earth Sciences / Geological Science) any other small hole, such as a space in a rock, soil, etc.

The American Heritage® Science Dictionary, Houghton Mifflin Company (2005).

> 1. A tiny opening, as one in an animal's skin or on the surface of a plant leaf or stem, through which liquids or gases may pass.
> 2. A space in soil, rock, or loose sediment that is not occupied by mineral matter and allows the passage or absorption of fluids, such as water, petroleum, or air.

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[6] The definitions of pore were accessed at www.thefreedictionary.com/pore on May 21, 2010.

The ordinary meaning of glass wool[7] is fine spun glass massed into a wool-like bulk. *E.g.*:

> *Collins English Dictionary – Complete and Unabridged* HarperCollins Publishers (1991).
> n. (Clothing, Personal Arts & Crafts / Textiles) fine spun glass massed into a wool-like bulk, used in insulation, filtering, etc.
>
> *The American Heritage® Dictionary of the English Language*, Fourth Edition, Houghton Mifflin Company (2000).
> n. Fine-spun fibers of glass used especially for insulation and in air filters.

We find no evidence that a person of ordinary skill in the art would think that wool has pores in the sense of minute openings in tissue. Put another way, we do not agree that a person of ordinary skill in the art would consider wool to be "microporous" in the ordinary sense of pore. We conclude that the interpretation of membrane as including glass wool is not reasonable in light of the Specification or the ordinary meanings of the terms.

We also agree with Appellants that the evidence the Examiner provided from Wang '742 does not support a relation to RNA purification. The Wang '742 Abstract was the only portion of Wang '742 the Examiner cited, and it relates to filtering solids from liquids, e.g., from blood. (FF 5.)

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[7] The definitions of glass wool were accessed at www.thefreedictionary.com/glass+wool on May 21, 2010.

CONCLUSIONS

The claim term "membrane" is not reasonably interpreted to include Sambrook's glass wool plug.

The cited Wang '742 Abstract does not support the finding that Wang '742 disclosed or suggested using a membrane as an RNA isolation column.

The evidence of record is insufficient to support a conclusion of prima facie obviousness.

SUMMARY

We reverse the rejection of claims 1, 3-6, 10-15, 20 and 21 under 35 U.S.C. § 103(a) over Sambrook, Wang '727, Wang '742 and Pall Life Sciences.

We reverse the rejection of claims 7-9 under 35 U.S.C. § 103(a) over Sambrook, Wang '727, Wang '742, Pall Life Sciences and Waggoner.

REVERSED

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